

Guillain-Barré Syndrome Among Adolescents Who Received Meningococcal Conjugate Vaccine

FACT SHEET for Healthcare Professionals

Updated December 20, 2005

What You Should Know

- The CDC and FDA, in partnership with state health departments, are investigating cases of Guillain-Barré syndrome (GBS) among adolescents who have recently received tetravalent (A, C, Y, W135) meningococcal conjugate vaccine (Meningococcal Polysaccharide Diphtheria Toxoid Conjugate Vaccine, Menactra, sanofi pasteur [MCV4]). As of December 19, 2005, the Vaccine Adverse Event Reporting System (VAERS) received seven reports of GBS in adolescents after receipt of MCV4 vaccination. All reported GBS cases occurred among persons aged 17-18 years who were vaccinated during June, July, or November 2005 and had symptom onset 11-31 days after MCV4 vaccination. The timing and onset of neurological symptoms are reasons to gather further information.
- The number of cases of GBS in adolescents who received MCV4 is not greater than would be expected in an unvaccinated adolescent population. An ongoing known risk for serious meningococcal disease exists. Therefore, CDC is recommending continuation of current vaccination strategies (www.cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm).
- CDC recommends that adolescents and their caregivers be informed of this ongoing investigation as part of the consent process for vaccination with MCV4. The updated Meningococcal Vaccine Information Statement (dated 10/7/05) should be used (www.cdc.gov/nip/publications/VIS/default.htm#mening).
- Whether receipt of MCV4 vaccine might increase the risk for recurrence of GBS is unknown. Persons with a history of GBS who are not in a high risk group for invasive meningococcal disease should not receive MCV4 (see Additional Facts: High Risk Group).
- FDA and CDC are requesting that providers or other persons with knowledge of possible cases of GBS (or other clinically significant adverse events) occurring after vaccination with MCV4 and/or other vaccines report them to VAERS. Reports should be submitted to VAERS at www.vaers.hhs.gov or by telephone at 800-822-7967.
- CDC further requests that healthcare providers report other cases of GBS (even those not associated with MCV4 or other vaccination) that occur among persons 11-19 years of age to state health departments in accordance with state or local disease-reporting guidelines. [Provisional case definitions for GBS](#) have been developed to assist public health and other medical personnel with GBS surveillance activities.

Additional Facts

- **Invasive meningococcal disease**

- Occurs in three common clinical forms: meningitis (49% of cases), blood infection (33%) and pneumonia (9%); other forms account for the remainder (9%) of the cases.
- Can have an abrupt onset with a rapid course of disease.
- Has a case fatality rate of 10%-14%; 11%-19% of survivors suffer serious sequelae including deafness, neurologic deficit, or limb loss.
- Affects approximately 1 in 100,000 people annually in the United States.
- Cases in the United States are almost all caused by *Neisseria meningitidis* bacteria serogroups B, C and Y.
- High risk groups for invasive meningococcal disease include
 - college freshmen living in dormitories
 - microbiologists who are routinely exposed to isolates of *N. meningitidis*
 - military recruits
 - persons who travel to or reside in countries in which *N. meningitidis* is hyperendemic or epidemic, particularly if contact with the local population will be prolonged
 - persons who have terminal complement component deficiencies
 - persons who have anatomic or functional asplenia

- **Meningococcal Vaccines**

- Two vaccines licensed in the United States protect against invasive meningococcal disease, tetravalent (A, C, Y, W135) meningococcal conjugate vaccine (MCV4) and tetravalent (A, C, Y, W135) meningococcal polysaccharide vaccine (MPS4). Differences between the vaccines can be reviewed at www.cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm
- There is currently no licensed vaccine that protects against serogroup B in the United States.
- Since February 2005, CDC's Advisory Committee on Immunization Practices (ACIP) has recommended routine vaccination of adolescents 11-12 years of age with MCV4. For adolescents who have not previously received MCV4, ACIP also recommends vaccination before high-school entry (at approximately age 15 years) as an effective strategy to reduce meningococcal disease incidence among adolescents and young adults.
- ACIP recommends routine vaccination with meningococcal vaccine (MCV4 preferred for persons 11-55 years of age, MPS4 acceptable) who are at high risk for meningococcal disease (see high risk groups above) and during meningococcal outbreaks caused by vaccine-preventable serogroups.
- Approximately 3.1 million doses of MCV4 have been distributed nationally since March 2005 (sanofi pasteur, unpublished data, 2005). Although the number of doses distributed is known, the exact number of vaccine doses administered is unknown.

- **Guillain-Barré syndrome (GBS)**

- GBS is a serious neurologic disorder involving inflammatory demyelination of peripheral nerves. It can occur spontaneously or after certain events such as infections.
- Illness is typically characterized by the subacute onset of progressive, symmetrical weakness in the legs and arms, with loss of reflexes. Sensory abnormalities, involvement of cranial nerves, and paralysis of respiratory muscles also can occur. A small proportion of patients die, and 20% of hospitalized patients can have prolonged disability.
- *Campylobacter jejuni*, which causes bacterial gastroenteritis is one identified precipitating factor for GBS.
- The precise rate of GBS in adolescents is unknown. Data from the Vaccine Safety Datalink (VSD), a collaborative project between CDC and eight managed care organizations in the United States, and the Health Care Utilization Project on GBS incidence in persons aged 11-19 years indicate a background annual incidence of 1-2 cases per 100,000 persons per year.
- This finding suggests that the rate of GBS among MCV4 recipients based on the number of cases reported within 6 weeks of administration of MCV4 is similar to what might have been expected to occur by chance alone. However, the timing of the onset of neurological symptoms (i.e., within 1.5-5 weeks of vaccination) is of concern.

For more information

For information about meningococcal vaccines, Guillain-Barré syndrome, meningococcal disease, and this investigation:

- View the CDC MMWR dispatch, Guillain-Barré Syndrome Among Recipients of Menactra® Meningococcal Conjugate Vaccine--United States, June--July 2005
www.cdc.gov/mmwr/preview/mmwrhtml/mm54d1006a1.htm
- View the Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices, 2005
www.cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm
- View the revised Vaccine Information Statement (VIS) for MCV4
<http://www.cdc.gov/nip/publications/VIS/default.htm>
- View the Meningococcal Disease fact sheet
www.cdc.gov/ncidod/dbmd/diseaseinfo/meningococcal_g.htm
- Visit the FDA and CDC Issue Alert on Menactra Meningococcal Vaccine and Guillain-Barré Syndrome
www.fda.gov/bbs/topics/news/2005/new01238.html
- View the American Academy of Pediatrics (AAP) Guillain-Barré Cases Among Recipients of Meningococcal Conjugate Vaccine: Interim Guidance for Physicians
www.cisimmunize.org/pro/doc/Guillain_COIDRecommendations.doc
- Visit the NIH Guillain-Barré Syndrome Fact Sheet
www.ninds.nih.gov/disorders/gbs/detail_gbs.htm

- Obtain the provisional case definitions for Guillain-Barré syndrome
www.cdc.gov/nip/vacsafe/concerns/gbs/gbs_case_defs.pdf

To report a case of Guillain-Barré Syndrome (or other clinically significant adverse event) occurring after vaccination to the Vaccine Adverse Event Reporting System,

- Visit <http://www.vaers.hhs.gov>
- Call 800-822-7967

For more information about vaccines and vaccinations:

- Call CDC-INFO Contact Center
 - English and Español: 800-CDC-INFO (800-232-4636)
 - TTY: 888-232-6348